DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 6, 2014

LINA Medical ApS
c/o Ms. Christine E. Nichols, RAC
Regulatory Affairs Manager
Boston Biomedical Associates
100 Crowley Drive, Suite 216
Marlborough, Massachusetts 01752

Re: K142538
Trade/Device Name: LINA SafeAir Smoke Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Device, Cutting & Coagulation & Accessories
Product Code: GEI
Dated: September 8, 2014
Received: September 9, 2014

Dear Ms. Nichols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Binita S. Ashar -S
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Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): **K142538**

Device Name: LiNA SafeAir Smoke Pencil

Indications for Use:

The LiNA SafeAir Smoke Pencil is designed for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Prescription Use__X__	AND/OR	Over-The-Counter Use _
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

5 510(k) Summary (K142538)

1. Submission Sponsor

LINA Medical ApS
Formervangen 5
2600 Glostrup
Denmark
Phone: +45 43 29 66 66
Fax: -45 43 29 66 99
Contact: Louisa Memborg, Regulatory Affairs Officer

Submission Correspondent

Christine E. Nichols RAC
Boston Biomedical Associates
100 Crowley Dr., Suite 216
Marlborough, MA 01752
Phone: 508-691-7046
Email: cnichols@boston-biomedical.com

Date Prepared

September 8, 2013

2. Device Identification

Trade/Proprietary Name:	LiNA SafeAir Smoke Pencil
Common/Usual Name:	electrosurgical, cutting & coagulation & accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	21 CFR 878.4400
Product Code:	GEI
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

3. Predicate Device

LiNA SafeAir Smoke Pencil K120454

4. Device Description

The SafeAir Smoke Pencil is a sterile single use integrated electrosurgical pencil and smoke evacuation hand piece that is packaged with an electrode blade. The device is designed for general electrosurgical applications including cutting and coagulating and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

The integration of the electrosurgical pencil and smoke evacuation enables the operator to activate an electrosurgical current as well as capture the smoke plume simultaneously.
The proposed device is the same as the predicate SafeAir Smoke Pencil. The only modification is a change to the labeling to allow the use of the Stryker® Colorado MicroDissection Needle electrodes in addition to the electrode that is packaged with the hand piece.

5. Indications for Use

The LiNA SafeAir Smoke Pencil is designed for general electrosurgical applications, including cutting and coagulation, and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

6. Comparison of Technological Characteristics with the Predicate Device

This special 510(k) is a modification to the labelling for the LiNA SafeAir Smoke Pencil previously cleared by the FDA with the 510(k) number (K120454). No changes were made to the intended use, indications for use, energy type, performance specifications, materials, sterilization method or fundamental scientific technology.

7. Performance Data

Non-Clinical Performance Data

Testing was performed to verify the compatibility of the Stryker Colorado MicroDissection Needle with the LiNA SafeAir Smoke Pencil hand piece. The testing demonstrated the proposed device met AAMI / ANSI / IEC 60601-2-2:2009, 201.15.4.1.102 for Compatibility of Third Party Electrodes, and demonstrated the hand piece delivers the electrosurgical current to the electrode for the desired surgical effect.

Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is the same as to the predicate device LiNA SafeAir Smoke Pencil. The descriptive information detailed in this submission supports the substantial equivalence of the device.

8. Conclusion Statement of Substantial Equivalence

The differences between the Modified LiNA SafeAir Smoke Pencil and the predicate LiNA SafeAir Smoke Pencil do not raise any new questions regarding its safety and effectiveness. Testing was performed including compatibility with third party electrodes and functional testing to demonstrate that the Colorado MicroDissection Needles can be used with the LiNA SafeAir Smoke Pencil. The Modified LiNA SafeAir Smoke Pencil is the same in terms of design, components, principal of operation, sterilization, biocompatibility, performance characteristics, and intended use as the predicate. The proposed Modified LiNA SafeAir Smoke Pencil, as designed, is determined to be at least as safe and effective as the referenced predicate device, which supports a determination of substantial equivalence.